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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,249	08/21/2001	Richard T. Lee	P0738/7001 (ERP/KA)	6506

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/934,249	Applicant(s) LEE ET AL.	
	Examiner Zachariah Lucas	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,8-11,68,80-83 and 86-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,8-11,68,80-83 and 86-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Currently claims 1-4, 8-11, 68, 80-83, and 86-90 are pending and under consideration in the application.
2. In the prior action, mailed on March 13, 2006, claims 1-4, 8-11, 68, 80-83, and 86-90 were pending and rejected.
3. In the Response of September 2006, the applicant amended claims 1 and 4.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. **(Prior Rejection- Maintained)** Claims 1-4, 8-11, 68, 80-83, 86-90 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Applicant traverses the rejection on the grounds that the sole basis of the rejection is the Examiner's doubt of the activity asserted by the Applicant. The Applicant asserts that this is not a proper ground for the rejection. The Applicant's attention is drawn to MPEP § 2164.04 which states, in part:

A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements

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contained therein which must be relied on for enabling support. Assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis.

Thus, the Applicant's argument is not found persuasive. Grounds for doubting the objective truth of the Applicant's asserted activity have been previously provided.

Moreover, it is noted that the Xu reference, applied as art in the prior actions, discloses a DNA encoding a protein identical to the MIVR-1 protein of the present application in the 250 C-terminal residues (i.e. varying therefrom in only the N-terminal 37 residues). The protein disclosed by Xu, referred to as PMEPA1, is disclosed as having activities associated with cell growth, and not apoptosis, thereby indicating that the MIVR-1 protein is likely to have similar functions. See e.g., Xu et al., Cancer Res 63: 4299-4304. Thus, the teachings of the Xu reference provide additional basis for doubting the objective truth of the asserted function of the disclosed MIVR-1 protein, and therefore of the presently claimed nucleic acids encoding it.

For these reasons, and the reasons of record, the rejection is maintained.

6. **(New Rejection- Necessitated by Amendment)** Claims 1, 3-4, 8-11, 68, 80-83, and 86-90 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For the purposes of this rejection, it is assumed that, contrary to the rejection above, the Applicant has established that the protein of SEQ ID NO: 1 (MIVR-1) has anti-apoptotic activity in cardiac cells.

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The claims have been amended to read on nucleic acids that encoding polypeptides having such activity, wherein the nucleic acids are at least 23 nucleotides in length and hybridize to the complement of SEQ ID NO: 1, or are fragment of SEQ ID NO: 1. Thus, the claims read on nucleic acids encoding amino acids of at least 7 amino acids in length that have anti-apoptotic activity in cardiac cells. Because the claim requires that the nucleic acids share some homology to SEQ ID NO: 1 but include the stringency hybridization, the claims read on nucleic acids that include variants of the MIVR-1 protein (or fragments thereof) encoded by SEQ ID NO: 1. Thus, the claims read on a genus of polynucleotides, including fragments and variants of SEQ ID NO: 1, that encode polypeptides having anti-apoptotic activity.

The following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Thus, when a claim covers a genus of inventions, the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed.

In the present case, the application discloses the sequence of SEQ ID NO: 1, and the fragment thereof actually encoding the MIVR-1 protein- SEQ ID NO: 3. However, the application neither discloses fragments of such that have anti-apoptotic activity, nor discloses any regions within the protein that correlate with the activity.

It is known in the art that the functions of proteins are determined by their sequences, and that certain regions within each protein are responsible for the protein's activity. Further, it is also known in the art that the effects of amino acid substitution in a protein are unpredictable. See e.g., Bowie et al., Science 248: 1306-10, esp. page 1306. The Bowie reference teaches that while proteins are generally tolerant of amino acid substitutions, the effects of any particular modification to a protein sequence are not predictable absent guidance as to the relationship between the amino acids to be modified, and the structure and/or function of the protein. In the present case, as indicated above, the application has not provided either an identification of those regions of the protein that are required for the protein's activity, or provided any guidance as to which residues may be removed or modified without a loss of function.

For these reasons, the claims as amended are rejected for lacking sufficient written description support for the claimed genus of nucleic acids.

Claim Rejections - 35 USC § 102

7. **(Prior Rejection- Withdrawn)** Claims 1, 4, 68, 81, 88, and 89 were rejected under 35 U.S.C. 102(a) as being anticipated by Xu et al., Genomics 66: 257-63. In view of the amendment to the claims, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

8. **(Prior Rejections- Withdrawn)** Claims 1, 4, 68, 80, 81, 88, and 89 were rejected under 35 U.S.C. 103(a) as being unpatentable over Xu as applied to claims 1, 4, 68, 81, and 88 previously, and further in view of the teachings of Kumar (U.S. 5,916,776) and Buck et al. (BioTechniques 27: 528-36). Claims 1, 4, 8-11, 80, 81, and 86-90 were rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al. as applied to claims 1, 4, 68, 80, 81, 88, and 89 above, and further in view of the teachings of Srivastava et al. (U.S. 6,566,130) and Lodish et al. (Molecular Cell Biology, 3rd Ed., 1995, pages 252-57). In view of the amendments to the claims, and the arguments presented in the Response, the rejections are withdrawn.

Conclusion

9. No claims are allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

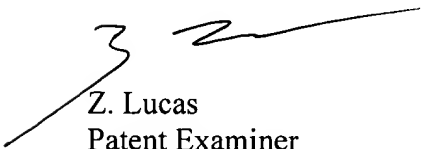
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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Z. Lucas
Patent Examiner



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